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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/678,414

10/02/2003

Lawrence M. Kauvar

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EXAMINER

WESSENDORF, TERESA D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/678,414

Applicant(s)

KAUVAR ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 43-51 is/are pending in the application.
- 4a) Of the above claim(s) 48 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-47, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of the following species: antibody, carboxamide and epitope/antibody made on 6/5/2006 are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 48 and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

***Status of Claims***

Claims 43-51 are pending

Claims 48 and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species.

Claims 43-47 and 50-51 are under examination.

***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Art Unit: 1639

**Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 43-47 and 50-51 are rejected on the ground of nonstatutory double patenting over claims of U. S. Patent No. 6,492,125 ('125 Patent) since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject

Art Unit: 1639

matter, as follows: a particulate label having a diameter of no more than 100nm.

The '125 Patent discloses at col. 7, lines 45-65:

The supporting particles are typically 0.1-1.mu.m in diameter and are preferably latex. However, smaller particles may also be used. A preferred range is 100-500, preferably 100-300, and more preferably 100-200 nm diameter particles. The particulate supports are generally spherical, and the microscopic techniques employed can distinguish spherical shapes from other general outlines.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 43-47 and 50-51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 8-9 of U.S. Patent No. 6,642,062 ('062 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '062 Patent claims the same particulate label except it does not claim the diameter for said label. However, the '062 Patent discloses said diameter as instantly claimed. (The two claims are so close in content that they both cover the same thing except for the instant diameter of the particulate label which is disclosed in the '062 particle label.)

Art Unit: 1639

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-47 and 50-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 43 is unclear as to whether the claim is drawn to a particulate label or to a particulate support comprised in said particulate label. The preamble recites a particulate label while the body of the claim recites the support. Furthermore, it is unclear as to the "particle" being referred to in the preceding statement. The term "magnitude" is a relative term which renders the claim indefinite. The term "magnitude" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to the extent each of the emitted signals is distinct from each other or the amount that differentiates one from the other hue and how it is varied

Art Unit: 1639

from one another. "The magnitude" lacks antecedent basis of support from the preceding statement.

2. Claim 50 is a duplicate of claim 43. The spatial arrangement of the particulate labels is but the same component recited in claim 43. It is not clear how a spatial arrangement makes the components of claim 43 different from claim 50.

3. Claim 51 does not further limit claim 50 and is drawn to more a method rather than to the product with a positive identifying feature of the particulate label.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Art Unit: 1639

Claims 43-47 and 50-51 rejected under 35 U.S.C. 102(e) as being anticipated by Chee et al (USP 7,033,754).

Chee discloses at e.g., col. 9, lines 62 up to col. 32, line 25, a microspheres or beads or particles which is defined as a small discrete particles. The composition of the beads vary, depending on the class of bioactive agent. Suitable bead compositions include those used in peptide e.g., latex. The bead sizes range from nanometers, i.e. 100 nm, to millimeters, i.e. 1 mm, with beads from about 0.2 micron to about 200 microns being preferred. In one embodiment, the DBL may be attached to a bead, i.e. a "decoder bead", that may carry a label such as a fluorophore. The use of multiple optical signatures increases the possible size of an array. In a preferred embodiment, the DBLs are either directly or indirectly labeled. By "labeled" is meant that a compound has at least one element, isotope or chemical compound attached to enable the detection of the compound. Examples of such labels include fluorophores. Decoding of self-assembled random arrays is done on the basis of pH titration. In this embodiment, in addition to bioactive agents, the beads comprise optical signatures, wherein the optical signatures are generated by the use of pH-responsive dyes (sometimes referred to herein as "pH dyes") such as fluorophores. This embodiment is similar to that outlined in PCT



Art Unit: 1639

US98/05025 and U.S.S.N. 09/151,877, both of which are expressly incorporated by reference, except that the dyes used in the present invention exhibits changes in fluorescence intensity (or other properties) when the solution pH is adjusted from below the pKa to above the pKa (or vice versa). Each bead can contain any subset of the pH dyes, and in this way a unique code for the bioactive agent is generated. In another preferred embodiment, a spatial or positional coding system is done. In this embodiment, there are sub-bundles or subarrays (i.e. portions of the total array) that are utilized. By analogy with the telephone system, each subarray is an "area code", that can have the same labels (i.e. telephone numbers) of other subarrays, that are separated by virtue of the location of the subarray. Thus, for example, the same unique labels can be reused from bundle to bundle. Thus, the use of 50 unique labels in combination with 100 different subarrays can form an array of 5000 different bioactive agents. In this embodiment, it becomes important to be able to identify one bundle from another; in general, this is done either manually or through the use of marker beads; these can be beads containing unique tags for each subarray, or the use of the same marker bead in differing amounts, or the use of two or more marker beads in different ratios. There are additional ways to increase the number of unique or distinct

Art Unit: 1639

tags. That is, the use of distinct attributes on each bead can be used to increase the number of codes. A variety of methods are used to generate a number of codes for use in the process of decoding the arrays, while minimizing the necessary decoding steps. For example, a variety of different coding strategies can be combined: thus, different "colors", combinations of colors ("hues"), different intensities of colors or hues or both, different colors and different bead sizes, etc. can all be combined. Alternatively, the number of distinct codes is markedly increased. In a preferred embodiment, the optical signature is generally a mixture of reporter dyes, preferably fluorescent. By varying both the composition of the mixture (i.e. the ratio of one dye to another) and the concentration of the dye (leading to differences in signal intensity), matrices of unique optical signatures may be generated. This may be done by covalently attaching the dyes to the surface of the beads. The dyes are preferably fluorescent dyes, which due to their strong signals provide a good signal-to-noise ratio for decoding. The encoding can be accomplished in a ratio of at least two dyes, although more encoding dimensions may be added in the size of the beads, for example. In addition, the labels are distinguishable from one another; thus two different labels may comprise different molecules (i.e. two different fluors) or,

Art Unit: 1639

alternatively, one label at two different concentrations or intensity. The dyes are covalently attached to the surface of the beads. This may be done as is generally outlined for the attachment of the bioactive agents, using functional groups on the surface of the beads. As will be appreciated by those in the art, these attachments are done to minimize the effect on the dye. A population of oligonucleotides encoding a single DBL is labeled with a defined ratio of colors such that each bead to which the DBL binds is identified based on a characteristic "hue" formulated from the combination of the colored fluorophores. Two or three or more distinct dyes (colors) are available for use. In this instance the number of differentiable codes generated by labeling a population of oligonucleotides encoding a single DBL with any given color is three. However by allowing combinations of colors and color levels in the labeling, many more codes are generated. With four primary colors and two intensity levels (color is present or absent), fifteen different hues/stage are possible. If four dyes and three different intensity levels are used, then 73 different hues/stage are possible. In this case, acquisition of only 4 color images is sufficient to obtain information on 73 different coding hues. See further the Examples starting at col. 51, which describes the details of the microspheres or beads.

Art Unit: 1639

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 43-47 and 50-51 are43-47 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chee in view of Haughland (USP 5,719,031) or applicants' disclosure of known prior art.

Chee is discussed above. Each of these references does not disclose the use of carboxamide as a linking agent. However Haughland discloses at col. 8, lines 1-10 that the covalent bond that attaches the dye to the polymer is selected to be generally resistant to spontaneous hydrolysis and also resistant to the degradation conditions being studied, e.g. to the action of the target enzyme(s); or, where required, to acid or base. Typically the covalent bond between the dye and the polymer is a carboxamide, sulfonamide, ether or thioether but any bond between the dye that is chemically stable and resistant to the

Art Unit: 1639

degradation conditions is suitable. Applicants state at page 9, lines 5-16 that "...standard linking techniques applicable to a multiplicity of substances and to the functional groups available on particulate supports include...amide linkages generated from carboxyl and amino functional groups. Other examples ....are as set forth in the catalog..."

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use carboxamide linkers in the support of Chee for the advantage taught by Haughland above. As recognized by applicants above, these linkers have been conventionally used in the art. One having ordinary skill in the art at the time of applicants' invention would be motivated to use carboxamide as a linker for the advantage taught by Haughland above, and its established used in the art as recognized by applicants' disclosure.

### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

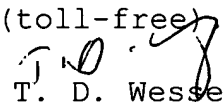
Walt et al disclose fiber optic sensors with encoded microspheres.

Art Unit: 1639

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

Tdw  
August 17, 2006